

Notice of Allowability

Application No.

09/258,600

Applicant(s)

FOWLKES ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/09/06.
2. ☒ The allowed claim(s) is/are 44-102 and 109.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa Hunter-Ensor, Ph.D. on July 12, 2006.

The application has been amended as follows:

In the claims:

Claim 55 (Amended) The yeast cell of claim 54 in which ~~the~~ an endogenous *SST2* gene is not functionally expressed.

Claim 56 (Amended) The yeast cell of claim 100, in which ~~the~~ an endogenous *FAR1* gene is not functionally expressed.

Claim 60 (Amended) The yeast cell of claim 58, wherein the homologous wild-type promoter is ~~the~~ an endogenous *FUS1* promoter.

Claim 61 (Amended) The yeast cell of claim 100 wherein the cells belongs to the species *Saccharomyces cerevisiae*.

Claim 64 (Amended) The method of claim 63 in which the cells comprise a pheromone-responsive selectable marker, and cells are selected for expression of a peptide having ~~the~~ a desired activating or inhibiting effect.

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Claim 65 (Amended) The method of claim 63 in which the cells comprise a pheromone-responsive screenable marker, and cells are screened for expression of a peptide having ~~the~~ a desired activating or inhibiting effect.

Claim 67 (Amended) A yeast cell having a pheromone system, which cell comprises:

(a) a first heterologous gene encoding a heterologous surrogate of a yeast pheromone receptor, wherein said surrogate is ~~the~~ a C5a receptor and performs in the pheromone system of the yeast cell a function naturally performed by said yeast pheromone receptor; and

(b) a second heterologous gene encoding a heterologous peptide, wherein said heterologous peptide modulates the interaction of said surrogate with said pheromone system in the yeast cell; and said modulation is a selectable or screenable event.

Claim 68 (Amended) A method of assaying a peptide for modulation of the activity of a non-yeast surrogate for a pheromone system protein, which comprises:

(a) providing yeast cells, wherein each of the yeast cells has a pheromone system and comprises:

(i) a first heterologous gene encoding a heterologous surrogate of a yeast pheromone receptor, wherein said surrogate is human Mdr1 receptor and performs in the pheromone system of the yeast cell a function naturally performed by said yeast pheromone receptor;

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(ii) a second heterologous gene encoding a heterologous peptide, wherein said heterologous peptide modulates the interaction of said surrogate with said pheromone system in the yeast cell; and

(iii) a pheromone-responsive selectable marker; wherein said modulation is a selectable or screenable event; and

wherein the cells grow on histidine-free media only if the surrogate transports α -factor, the cells are galactose-sensitive only if the surrogate transports α -factor, and endogenous pleiotropic drug resistance genes have been inactivated;

(b) determining by detecting a change in said selectable or screenable event whether the pheromone signal pathway is activated or inhibited by the interaction; and

(c) selecting said cells selected for expression of a peptide having ~~the~~ a desired activating or inhibiting effect, thereby assaying a peptide for modulation of the activity of a non-yeast surrogate for a pheromone system protein.

Claim 69 (Amended) A mixture of recombinant yeast cells, each cell of which comprises a yeast cell according to claim 100, wherein collectively the mixture of cells expresses a library of said heterologous peptides, and modulation of the pheromone system by the heterologous peptide provides ~~the~~ a detectable signal.

Claim 70 (Amended) The mixture of recombinant yeast cells of claim 69, wherein the yeast pheromone receptor is inactivated.

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Claim 71 (Amended) The mixture of recombinant yeast cells of claim 69, wherein each cell further comprises a marker gene construct containing a marker gene in operative linkage with one or more transcriptional regulatory elements responsive to the pheromone system, expression of the marker gene providing the a detectable signal.

Claim 72 (Amended) The mixture of recombinant yeast cells of claim 71, wherein the marker gene that gives rise to a detectable signal selected from the group consisting of β galactosidase, alkaline phosphatase, horseradish peroxidase, exoglucanase, luciferase and chloramphenicol acetyl transferase.

Claim 73 (Amended) The mixture of recombinant yeast cells of claim 71, wherein the marker gene that gives rise to a detectable signal is a *HIS3* gene.

Claim 74 (Amended) The mixture of recombinant yeast cells of claim 69, wherein the population of heterologous peptides includes at least 10^3 different peptide sequences.

Claim 75 (Amended) The mixture of recombinant yeast cells of claim 69, wherein the population of heterologous peptides includes at least 10^7 different peptide sequences.

Claim 76 (Amended) The mixture of recombinant yeast cells of claim 69, wherein the yeast cells is are a *Saccharomyces* cells.

Claim 77 (Amended) A mixture of recombinant yeast cells, each cell of which comprises a yeast cell according to claim 100, wherein said yeast cell further comprises an expressible gene construct encoding a heterologous peptide, said heterologous peptide including a signal sequence for secretion into

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the periplasmic space, wherein collectively the mixture of cells expresses a library of said heterologous peptides, and modulation of the pheromone system by the heterologous peptide provides the a detectable signal.

Claim 78 (Amended) The mixture of recombinant yeast cells of claim 77, wherein the yeast pheromone system is inactivated.

Claim 79 (Amended) The mixture of recombinant yeast cells of claim 77, wherein each cell further comprises a marker gene construct containing a marker gene in operative linkage with one or more transcriptional regulatory elements responsive to the pheromone system, expression of the marker gene providing the detectable signal.

Claim 80 (Amended) The mixture of recombinant yeast cells of claim 79, wherein the marker gene that gives rise to a detectable signal selected from the group consisting of β galactosidase, alkaline phosphatase, horseradish peroxidase, exoglucanase, luciferase and chloramphenicol acetyl transferase.

Claim 81 (Amended) The mixture of recombinant yeast cells of claim 79, wherein the marker gene that gives rise to a detectable signal is a *HIS3* gene.

Claim 82 (Amended) The mixture of recombinant yeast cells of claim 77, wherein the population of heterologous peptides includes at least 10^3 different peptide sequences.

Claim 83 (Amended) The mixture of recombinant yeast cells of claim 77, wherein the population of heterologous peptides includes at least 10^7 different peptide sequences.

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Claim 84 (Amended) The mixture of recombinant yeast cells of claim 77, wherein the yeast cells is are ~~a~~ *Saccharomyces* cells.

Claim 100 (Amended) A yeast cell having a pheromone system, which cell comprises:

(a) a first heterologous gene encoding a heterologous surrogate of a yeast pheromone receptor, said surrogate performing in the pheromone system of the yeast cell a function naturally performed by said yeast pheromone receptor, and

(b) a second heterologous gene encoding a heterologous peptide, wherein said heterologous peptide modulates the interaction of said surrogate with said pheromone system in the yeast cell; and said modulation is a selectable or screenable event, and wherein said heterologous ~~polypeptide~~ peptide is selected from the group consisting of agonists for the surrogate receptor and antagonists of the surrogate receptor.

Claim 101 (Amended) A yeast cell having a pheromone system, which cell comprises:

(a) a first heterologous gene encoding a heterologous surrogate of a yeast pheromone receptor, said surrogate performing in the pheromone system of the yeast cell a function naturally performed by said yeast pheromone receptor; and

(b) a second heterologous gene encoding a heterologous peptide, wherein said heterologous peptide modulates the interaction of said surrogate with said pheromone system in the yeast cell; and said modulation is a selectable or screenable event, and wherein said heterologous ~~polypeptide~~ peptide is selected

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from the group consisting of agonists for the surrogate receptor and antagonists of the surrogate receptor; and

(c) a chimeric $G\alpha$ subunit, wherein the amino terminal portion of the $G\alpha$ subunit is substantially homologous with the $G\alpha$ subunit of a yeast G protein and the remainder is substantially homologous with corresponding portion of a $G\alpha$ subunit of a heterologous G protein.

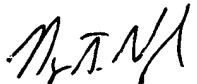
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NANCY VOGEL
PRIMARY EXAMINER